

REMARKS

In response to the Office Action dated January 26, 2007, Applicants respectfully request that the above amendments be entered and the following remarks be considered. Claims 1-3, 7-14, 17, 18 and 21-24 are currently pending in the application. Claims 4, 5 and 19 have been canceled. Claims 1-3, 7-14, 17, 18 and 21-24 are believed to be in condition for allowance and such favorable action is respectfully requested.

Objections

Table 1 has been objected to as it is stated that Table 1 does not correspond to information presented in Table 2. Applicants respectfully traverse this objection.

Table 1 depicts the total number of patients tested and Table 2 depicts the number of UC and CD patients who tested positive for fecal ANCA and the 7 IBS and 11 healthy patients tested. Table 2 displays a subset of the population depicted in Table 1. In particular, Table 2 only includes UC and CD patients who tested positive for ANCA, it does not include UC and CD patients who tested negative for ANCA. As such, there is not a disappearance of patients from Table 1 to Table 2.

It is stated that the information presented in Table 2 does not correspond with Table 3. Table 2 depicts the UC and CD patients who tested positive for fecal ANCA and all 7 IBS and 11 healthy patients tested. Table 3 includes all patients tested for ANCA, not just those who tested positive for fecal ANCA.

As the Tables correctly list the data, Applicants request withdrawal of the objection to Tables 1-3.

35 U.S.C. § 112, Second Paragraph, Rejections

Claims 3, 11-14 and 18 have been rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 3 and 18 have been rejected for the use of the infinitive "to differentiate." Claims 3 and 18 have been amended to include an act of differentiating. As such, Applicants submit that the language is definite and request withdrawal of the §112 rejection of these claims.

Claim 11 has been rejected for an unclear preamble. Applicants have amended the preamble accordingly and request withdrawal of this rejection.

Claim rejections 35 USC § 101

Claims 1-3, 7-14, 17, 18 and 21-24 have been rejected under 35 USC § 101 stating the claimed invention lacks credible utility. Applicants respectfully traverse this rejection and assert that the claimed invention has patentable utility.

According to MPEP 2107.01 "[p]ractical utility is a shorthand way of attributing 'real-world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public. *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)." Applicant submits that the method for testing a fecal sample for an elevated level of anti-neutrophil cytoplasmic antibodies, wherein an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis provides a benefit to the public and is consistent with the logic underlying Applicants' assertion.

According to the Office Action is stated that Applicant's assertion of specific utility is not credible because, according to Table 4 of Applicant's specification, only 41% of patients presenting with UC possessed ANCA (i.e., ANCA is a useful indicator of ulcerative

colitis.) However, Applicants submit that they are not claiming that all patients' with ulcerative colitis test possess ANCA and this statement is utilizing the reverse logic.

In particular, Applicants have amended claims 1, 11 and 17 to be directed to testing the fecal sample of a patient presenting with inflammatory bowel disease. Applicants are claiming if a patient's sample contains elevated level of anti-neutrophil cytoplasmic antibodies, the elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis. Thus, while not all patients with UC have an elevated level of ANCA, those who do have an elevated level can be diagnosed with UC, rather than Crohn's disease. Thus, while the test only detects ANCA in 41% of UC patients (Sensitivity), in the 41% of the patients who have ANCA, the test is 92% accurate in diagnosing UC (Specificity). The specificity refers to how well a positive result of ANCA correlates to a diagnosis of UC.

Furthermore, according to MPEP 2107.01, "[p]ractical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be 'useful.' Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is 'useful' for a particular reason." Applicants respectfully submit that the invention as claimed is "useful" as described above and request withdrawal of the §101 rejection of claims 1-3, 6-14, 17, 18 and 20-24.

Claim rejections 35 USC §112, first paragraph

Claims 1-3, 7-14, 17-18 and 21-24 have been rejected under 35 USC §112, first paragraph stating that the claimed invention is not set forth by a credibly-asserted utility. Applicants submit that the claimed invention has a specific credibly-asserted utility as stated with reference to the §101 rejection. As such, Applicants request withdrawal of the §112 rejection of claims 1-3, 6-14, 17, 18 and 20-24.

CONCLUSION

Each of claims 1-3 7-14 and 17, 18 and 21-24 is believed to be in condition for allowance, and a timely notice of allowance solicited. Should it be determined that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicants' undersigned attorney.

The fee for a three-month extension of time is submitted herewith. It is believed that no additional fee is due in conjunction with the present Amendment. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required or credit any overpayment, to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100294.

Respectfully submitted,

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